REMARKS

Applicant has amended the title as suggested by the Examiner.

Applicant presents a replacement paragraph to correct a typographical error. The concentration of sodium citrate was corrected from 0.15M to 0.015M. Support for this amendment can be found in either of the two references cited in this paragraph.

Claims 1-9, 12, 16, 20, 24, 25, 32, 34 and 36 were previously pending in this application. By this amendment, Applicant is canceling claims 16, 20, 24, 25, 32 and 36 without prejudice or disclaimer. Claims 1, 6 and 12 have been amended. Support for these amendments can be found at least on page 14, lines 21-27 and page 9, lines 13-14. Claims 2,3 and 5 have been withdrawn as a result of the restriction requirement. As a result claims 1, 4, 6-9, 12 and 34 are pending for examination with claims 1 and 6 being independent claims. No new matter has been added.

This Amendment is filed in response to the communication regarding non-compliance of the Amendment mailed October 13, 2004. The present Amendment is identical to the previously-filed Amendment except for the items that the Examiner noted in the non-compliance.

Rejection Under 35 U.S.C. §101

Claims 1, 4, 6-9, 12 and 34 are rejected under 35 U.S.C. §101 for being drawn to an invention with no apparent or disclosed specific and credible utility. According to the Examiner, the instant application does not disclose a specific biological role for the DNA encoded protein described.

The Applicant respectfully disagrees with this rejection and holds that the Applicant teaches a biological activity of SOC/CRAC2. The Applicant respectfully reminds the Examiner that "real world utility" is not a litmus test for patentability. Page 2, lines 23-30 of the application states that the ion channel sequences of the invention are useful in identifying drugs that can be used to block lymphocyte proliferation. At page 45, line 23 to page 46, line 10 of the specification, the Applicant has presented examples of a procedure that can be used to assess pharmacological reagents for inhibition of SOC/CRAC channel function in mast cells and also show that a known calcium ion channel blocker sphingosine, inhibits SOC/CRAC calcium influx (see page 47, lines 7-9). Example 1, page 46, shows SOC/CRAC expression enhances

thapsigargin-dependent calcium influx and enhances the amount of intracellular calcium stores. Example 4, page 47, indicates that SOC-2/CRAC-1 (SEQ ID NO:1) is required for cell viability (page 47, lines 10-18). The Applicant has further presented guidance on the use of nucleic acid molecules as probes and primers to identify additional members of the SOC/CRAC family of calcium channels, as diagnostic reagents for identifying the presence of SOC/CRAC polypeptides in biological or other samples, and for generating SOC/CRAC polypeptides that can be used as reagents in diagnostic and therapeutic assays to identify the presence, absence, and/or amounts of a SOC/CRAC nucleic acid or polypeptide in a biological or other sample (see page 13, lines 17-23).

In addition, the Applicant brings the following articles to the Examiner's attention (Wülfing C., et al., Proc. Natl. Acad. Sci. U.S.A., 95:6302-6307, 1998; Roitt, I. M. et al., Immunology, Second Edition, Harper & Row Publishers, New York, 1989) which are believed to support Applicant's assertions concerning utility. The article by Wülfing et al. studied intracellular calcium levels in the T cell and the interaction of LFA-1 and ICAM-1. Wülfing et al. indicated that elevation of calcium ions in T cells is critical for T cell activation (see abstract and page 6306, column 2, last paragraph). This article supports the utility of the SOC/CRAC polypeptides of the invention because identifying reagents that inhibit SOC/CRAC calcium influx would be useful for immune system suppression for example after organ transplantation, treating autoimmune disorders, and treatment of inflammatory disorders.

Furthermore the article by Roitt et al. describes antigen-induced calcium ion influx into mast cells causing the release of histamine. Hypersecretion of histamine is one cause of asthma and one treatment available is sodium cromoglycate which is believed to prevent histamine release by blocking calcium ion influx. The SOC/CRAC polypeptides of the invention could be used to identify drugs that would be useful for treating asthma and other allergic disorders.

Therefore, the application provides specific, substantial, well-known and credible utilities for the claimed invention. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1, 4, 6-9, 12 and 34 are rejected under 35 U.S.C. §112, first paragraph. Specifically the claims are rejected because one of skill in the art would not know how to use the

claimed invention and particular reference is made to claim 34. The Applicant respectfully traverses the rejection.

The Applicant has provided novel SOC/CRAC polypeptide and nucleic acid molecules that are calcium channel polypeptides. The Applicant has provided guidance for various utilities of the nucleic acid molecules as noted above. Guidance is further provided for the use of SOC/CRAC-specific binding agents as useful in a variety of diagnostic and therapeutic applications where disease or disease prognosis is associated with altered SOC/CRAC and SOC/CRAC calcium channel fluxing characteristics (see page 39, lines 25-33). In view of the polypeptide and nucleic acid molecules together with the guidance provided in the instant application for their use, one of skill in the art would not be required to exercise undue experimentation to practice the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1, 6-9, 12 and 34 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification so as to convey to one skilled in the art that the inventor was in possession of the claimed invention at the time the application was filed. Specifically, the Examiner states that "it is clear that Applicant has possession of and what Applicant is claiming" but according to the Examiner there is a lack of guidance regarding structure and function of the claimed nucleic acid molecules.

The Applicant respectfully disagrees with this rejection. The instant application provides a method for determining structurally similar nucleic acid molecules using hybridization. The Applicant provides details of hybridization conditions on page 14, lines 21-27 which would allow one of ordinary skill in the art the means to determine structural similarity between nucleic acid molecules. Hybridization is indicative of a structural relation between nucleic acid molecules. The Applicant has amended the claims to include the stringent hybridization conditions. One of skill in the art would know that the Applicant was in possession of such nucleic acid molecules.

On the issue of degeneracy raised by the Examiner, the Applicant has provided amino acid sequence data which would allow one of ordinary skill in the art the information required to determine further structurally related nucleic acid molecules. The amino acid sequence describes

a set of nucleic acid molecules that encode it, as is well-known in the art. Therefore one of skill in the art would know that the Applicant was in possession of such nucleic acid molecules.

Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1, 4, 9, 12 and 34 are further rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement for containing subject matter that was not described in the specification in a way to enable one skilled in the art to make and /or use the invention. Specifically the rejection is based upon the Examiner's assertion that the prior art does not teach how to produce a polypeptide by using a nucleic acid that is complementary to a nucleic acid encoding that polypeptide.

The Applicant respectfully disagrees with this rejection because one of ordinary skill in the art would know that a coding strand is required to make a complement strand. The production of a polypeptide from a coding strand nucleic acid is standard practice for one of ordinary skill in the art. The complement strand encodes the coding strand that as mRNA encodes the protein. There are several programs available and known to those of skill in the art to translate a complement nucleic acid to the coding strand for that nucleic acid and this can be performed with no more than ordinary skill. Furthermore, claim 1 subsection (d) recites complements of the nucleic acid sequence which encode for SOC/CRAC proteins. Translation products of SOC/CRAC proteins are provided in the sequence listing and one of skill in the art would be able to translate this sequence to produce the complement sequence using the aforementioned methods.

Accordingly, withdrawal of this rejection is respectfully requested.

Claims 9 and 12 are also rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement for containing subject matter that was not described in the specification in a way to enable one skilled in the art to make and /or use the invention. Specifically, the Examiner has objected to the use of the term "fragment" in that it encompasses fragments as short as one nucleotide which do not encode any amino acid, peptide or polypeptide.

The Applicant has amended claim 6 to add a lower limit of at least 12 nucleotides for the length of the fragment. The Applicant respectfully refers the Examiner to pages 13 and 17 of the instant application. On page 13, lines 8-12 and on page 17, lines 13-19, Applicant has provided guidance for the size of a fragment. Support for this amendment can be found on page 17, lines 14-19, which also provides that a fragment can be up to and including the entire length of the disclosed sequence. Support can also be found on page 13, lines 8-12 which provides a range of size from at least 8 nucleotides up to and including 1000 nucleotides.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1, 4, 6-9, 12 and 34 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

i). Specifically claim 1 has been rejected for recitation of hybridization "under stringent conditions." Applicant has amended claim 1 to recite hybridization conditions. Support for this amendment can be found on page 14, lines 21-27.

ii). Claims 1 and 12 have been rejected as being vague and indefinite for use of the term SOC/CRAC without reference to a SEQ ID NO:. Applicant has amended claim 1 to include the phrase "calcium channel." Support for this amendment can be found at least on page 9, lines 23-30, and pages 9-10, abridging paragraph.

iii). Claim 1 has been further rejected for being vague and indefinite with respect to section (b) which refers to "deletions, additions and substitutions of (a)." Applicant has amended claim 1 and subsection (a) recites nucleic acid sequence. Subsection (b) of claim 1 incorporates subsection (a) and is therefore a nucleic acid sequence as recited in (a) having deletions, additions and substitutions. Support for this may be found at least on page 25, lines 13-15 of the application.

iv). Claims 6 and 12 have been rejected as being vague and indefinite for the recitation of "unique fragment." Applicant has amended claim 6 and 12 to delete the term "unique" from the claims.

v). Claim 6 has been further rejected as being indefinite for the recitation of "a sequence [ ] which is not identical to any sequence." One of ordinary skill in the art would be able to

obtain sequence information from an accession number by using methods well known in the art, for example using the GenBank website to search the accession number and hence obtain the sequence information.

vi). Claim 6 has been rejected as being ambiguous and indefinite for the recitation of "(3) fragments of [unique fragment of (a)]." The Examiner has requested clarification as to the metes and bounds of "a fragment" recited in (3). The Applicant has amended claim 6 to add the phrase "at least 12 or more nucleotides in length." Support for this amendment can be found on page 17, lines 14-19, which provides that a fragment can be at least 12 nucleotides in length and up to the entire length of the disclosed sequence.

vii). Claim 34 has been rejected for being vague and ambiguous for recitation of "expression product" in that claim 1 from which it depends encompasses nucleic acid molecules that do not express any products and the Examiner has requested clarification. The Applicant respectfully disagrees because expression products not only include polypeptides but also other nucleic acids, such as antisense, dsRNA for RNAi etc.. Support for this can be found on page 18, second full paragraph.

Accordingly, withdrawal of these rejections is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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